and 29 are pending. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made**".

I. Rejection of Claims under 35 USC 112

In an Office Action dated June 31, 2002, the Examiner rejects the Applicant's claimed invention because "the specification only teaches that the feed can be used to treat or prevent bacterial infections in chickens, but there is absolutely no disclosure of isolating or identifying out the chickens that are sick and treating them specifically for the infection." Since the Applicant has amended the claims, such that sick chickens are no longer identified and isolated, the enablement rejection is inapplicable. The invention is fully enabled because the Applicant is claiming the new use of treating or preventing bacterial infections with feed containing xylanase.

II. Rejections of Claims under 35 USC 102

The Examiner argues that the invention is anticipated because the cited references teach that xylanase may be used as a feed additive to aid animals in digestion. The Examiner argues that such a use of xylanase as a feed additive would inherently prevent or treat bacterial infections. However, because the Applicant's invention relates to a new method of medical treatment, such an application of the inherency doctrine is not consistent with current case law.

A. To Anticipate th Asserted Inherent Characteristic Must be Recognized By Those Reasonably Skilled in the Art

The doctrine of inherency "accomodates situations where the common knowledge of technologists is not recorded in the reference." Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991). Therefore, it is intended to address situations where a reference is silent as to a particular characteristic, but the presence of such a characteristic is considered well known or part of the common knowledge of those of ordinary skill in the art.

Based on this rationale, the doctrine provides that inherent anticipation does not occur when persons of ordinary skill in the art do not recognize the claimed inherent characteristic as being present in the prior art reference. In order for a reference to anticipate when the reference is silent about the asserted inherent characteristic, such a gap may be filled with extrinsic evidence but "[s]uch evidence must make it clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991) (emphasis added); see also Glaxo, Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047 (Fed. Cir. 1995). In other words, although an asserted inherent characteristic may serve to anticipate, in order to do so the asserted inherent characteristic must be recognized by those reasonably skilled in the art.

The Examiner argues that the presence of xylanase in animal feed, as a feed additive as taught in the cited references, would inherently prevent or treat bacterial infections. However, even if such a characteristic were to be

present in the prior art feed additive, such a characteristic would not be recognized as inherent by persons of ordinary skill in the art as is required for anticipation. On the contrary, the effectiveness of xylanase in the prevention and treatment of bacterial infections in animals was unknown prior to the Applicant's present invention. Such a lack of recognition of even the potential prevention and treatment characteristics of xylanase is clearly evidenced by the previously routine practice of adding antibiotics to animal feed to prevent and treat bacterial infections. Had those of ordinary skill in the art recognized the prevention and treatment benefit of xylanase as a characteristic inherent to the enzyme, the addition of antibiotics would have been unnecessary and redundant. Since the ability of xyalanse to effectively prevent and treat bacterial infections was not recognized by those reasonably skilled in the art prior to Applicant's invention, this ability cannot be considered "inherent" for purposes of anticipation under the inherency doctrine.

B. A New Use of a Known Compound is Patentable

It is well settled that a new use of a known compound is patentable. While the discovery of a new use for an old compound does not make the compound itself patentable, such a discovery may be patentable to the discover as a process or method of use. In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986), citing In re Hack, 245 F.2d 246, 248 (C.C.P.A. 1957). It has been recognized "that it often requires perceptivity and intuitive genius of the highest order to grasp the idea that a ... material in one art may be used in another" and that inventive faculties may be brought to bear in such a case

as they would "in the creation of a device de novo." In re Hack, 245 F.2d 246, 48 (C.C.P.A. 1957). Based upon this line of thinking, numerous patents have been allowed describing a new use of a known compound. Some examples include:

i. Fluoxetine was described as an antidepressant (U.S. 4,018,895) and then nearly ten years later patented in connection with a method for treating anxiety (U.S. 4,590,213).

ii. Deramciclane was described as an antidepressent (U.S. 4,342,762) and described as having anxiolytic properties in a scientific publication. Subsequently, patents issued (U.S. . 6,335,371 and 6,335,372) to methods of inducing cognition enhancement using deramciclane.

iii. Amlodipine, known to be an anti-ischaemic agent and an antihypertensive agent (US 4,572,909), was later patented as a medicament for treating congestive heart failure (US 5,155,120).

iv. Finasteride, known to be useful for the treatment of hyperandrogenic conditions (US 4,760,071) was found to be patentable in treating androgenica alopecia (US 5,571,817) and in decreasing atherosclerosis and its complications (US 6,090,409).

v. Droloxifene, described to be useful as an anti-tumor agent, particularly as a remedy for tumors of the breast (EP 0054 168, corresponding to US 5,047,431 granted Sep.10, 1991) was found to be patentable in treating bone diseases (US 5,254,594).

vi. Toremifene, a nonsteroidal anti-estrogen compound, described to be useful for treating hormone-dependent tumors (US 4,696,949), was found to be patentable in treating autoimmune diseases such as systemic lupus eryematodes (US 5,886,049, foreign priority from Oct. 27, 1992), autoimmune diseases affecting the blood vessels (US 6,184,253, foreign

priority from Oct. 27, 1992), autoimmune diseases affecting the salivary glands (US 6,355,688, foreign priority from Oct. 27, 1992) and autoimmune degenerative diseases of joints (US 6,387,958, foreign priority from Oct. 27, 1992).

In each of the above examples, the second medical use that was patented could have arisen when carrying out the first claimed medical use. In particular, fluoxetine would inevitably have treated anxiety, which often arises in those suffering from depression, while it was being used as an anti-depressant. Likewise, deramciclane would have induced the enhancement of cognition when it was used as an anti-depressant. The remaining examples follow a similar pattern. In each case, the prior art did not make the second medical use available to a person skilled in the art and, as such, the prior art did not act as a bar to later patents directed to new medical uses. In precisely the same way, the present invention makes the use of xylanase to treat and prevent bacterial infections available to a person skilled in the art, whereas in the past no such use was known. Accordingly, the present invention is not anticipated because it is a new, and previously unknown, use of xylanase/cellulase and such an invention is patentable under the prior practice of the Patent and Trademark Office as is exemplified in the examples noted above.

III. Rejection of Claims under 35 USC 103

The Examiner argues that the invention is obvious because the combined references teach "feeding chickens feed which contains xylanase that improves utilization of feed by the chickens." The Examiner further argues that "when feeding the

chickens the xylanase feed it would have been obvious to identify the chickens that are sick... and it would have been obvious to continue feeding the sick chickens for the same reason as feeding it to the healthy chickens since the feed makes the chickens grow better and be healthier." Thus, the Examiner concludes that "obviously chickens that are healthier resist infection better." However, if a xylanase/cellulase containing feed did not treat an infection caused by *Salmonella*, *Campylobacter*, and/or *Clostridium perfringens* by reducing the ability of these bacteria to colonize the intestines of the animal, and thus reducing the level of infection, a sick chicken would not get better and grow. On the contrary, it would suffer from diarrhea and other symptoms caused by infection and would continue to lose weight and remain sick despite being fed. The majority of the references cited by the Examiner at most describe only the use of xylanase in feed to improve the ability of animals to digest the food, thus reducing the farmer's feed bill. However, none of the cited references describe a method for using feed containing xylanase to treat or prevent infections caused by bacteria as claimed by the Applicant.

A. Prevention & Treatment of Bacterial Infections by Chicken Feed Containing Xylanase is Unknown

Obviousness cannot be predicated on what is unknown. In re Sportmann, 363 F.2d 444,448 (C.C.P.A. 1966) ; W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1555 (Fed. Cir. 1983). Here the "unknown" is the prevention or treatment of bacterial infections using feed containing xylanase. The Examiner sidesteps the unknown by attempting to show that xylanase improves the utilization of feed by chickens, thus

when sick and healthy chickens eat the feed they experience increased growth, better health, and resistance to infection. Essentially, the Examiner argues that the advantage of treating or preventing bacterial infections was an existing characteristic of the chicken feed containing xylanase therefore it was obvious. However, because it was an unknown advantage it cannot support an obvious rejection. Therefore, using xylanase feed to prevent and treat bacterial infections is not obvious.

The Applicant is not claiming a xylanase feed for animals. Rather, the Applicant is claiming a new "unknown" use for the feed, in the form of method claims. The Applicant's invention is not a new process for feeding chickens xylanase feed but a new method for using the feed to treat or prevent bacterial infections.

B. No Relationship between the Use Taught in the Reference and the Use Discovered.

Obviousness requires some relationship between the use taught in the reference and the use discovered by the applicant. In re Dillion, 892 F.2d 1554, 1570 (Fed.Cir. 1989). The references cited by the Examiner discloses using chicken feed containing xylanase in connection with increased or aided digestion and treatment of coccidiosis. The use disclosed by the Applicant is using chicken feed containing xylanase to prevent or treat bacterial infections. One of ordinary skill in the art would not assume a digestive aid, as described in GB '867, US '055 and US '500 would also prevent or treat bacterial infections. Moreover, none of the references or combination of references describes or suggests such a relationship between the uses. Thus, the method of

using xylanase feed for preventing or treating bacterial infections in chickens is unexpected as compared with the prior art. The applicant's use for utilizing the xylanase feed in the prevention or treatment of bacterial infections is unrelated to the known utility and thus is nonobvious.

C. Applicant is Fulfilling a Long Felt Need

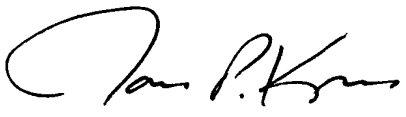
As the specification suggests there is a long felt need in chicken industry to provide for the prevention and treatment of bacterial infections. Specifically, for discovering a method for preventing and treating bacterial infections that does not include using antibiotics. Because nothing in the prior art reveals using feed containing xylanase for such a use and the persistent long felt need in the industry to resolve this problem, the Applicant's claimed invention is nonobvious.

Additionally, where the reason for the practice suggested by the prior art is much less significant than the reason derived from the inventor's solution to another problem, the results may be so unexpected as to support a conclusion of nonobviousness. Solder Removal Co. v. United States Int'l Trade Comm'n, 582 F.2d 628, 635 (C.C.P.A. 1978). The references cited by the Examiner disclose using chicken feed containing xylanase in connection with increased or aided digestion and treatment of coccidiosis. Because of the long felt need in the industry to prevent and treat bacterial infections without antibiotics, the Applicant's invention is more significant. Since the Applicant's use is more significant than other known uses of feed containing xylanase, the Applicant's invention is nonobvious.

Applicants respectfully request that in view of the amendments and remarks made herein that the pending claims be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required in this application to Deposit Account No. 06-1135.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By 

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VERSION WITH BRACKETS AND UNDERLINING

1. (Three times amended) A method for treating or preventing a bacterial infection in a chicken caused by a bacteria selected from the group consisting of *Salmonella, Campylobacter, Clostridium perfringens*, and mixtures thereof, the method comprising:

[identifying chickens having a bacterial infection caused by a bacteria selected from the group consisting of *Salmonella, Camphylobacter, Clostridium perfringes*, and mixtures thereof;]

feeding the chickens [identified as having a bacterial infection] an animal feed comprising xylanase in an amount effective for treating or preventing the bacterial infection.

21. (Twice amended) A method for treating or preventing a bacterial infection in a chicken caused by a bacteria selected from the group consisting of *Salmonella, Campylobacter, Clostridium perfringens* and mixtures thereof, the method comprising:

[identifying chickens having a bacterial infection caused by a bacteria selected from the group consisting of *Salmonella, Camphylobacter, Clostridium perfringes*, and mixtures thereof;]

feeding the chicken [identified as having a bacterial infection] an animal feed which comprises a cellulase and at least about 25% by weight of a cereal selected from the group consisting of wheat, maize, rye, barley, oats, triticale, rice, sorghum and mixtures thereof, the cellulase being included in the animal feed in an amount effective for treating or preventing the bacterial infection.

29. (Twice amended) A method for treating or preventing a bacterial infection in chickens caused by a bacteria selected from the group consisting of *Salmonella, Campylobacter, Clostridium perfringens,* and mixtures thereof, the method comprising:

[identifying chickens having a bacterial infection caused by a bacteria selected from the group consisting of *Salmonella, Camphylobacter, Clostridium perfringens*, and mixtures thereof;]

feeding the chicken [identified as having a bacterial infection] an animal feed which comprises a β-glucanase and at least about 25% by weight wheat, the β-glucanase being included in the animal feed in an amount effective for treating or preventing the bacterial infection.